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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61B 17/39 — A1

(11) International Publication Number: WO 99/18870

(43) International Publication Date: 22 April 1999 (22.04.99)

(21) International Application Number: PCT/US98/21440

(22) International Filing Date: 9 October 1998 (09.10.98)

(30) Priority Data:
60/062,954 10 October 1997 (10.10.97) US

(63) Related by Continuation (CON) or Continuation-in-Part (CIP) to Earlier Application
US 60/062,954 (CON)
Filed on 10 October 1997 (10.10.97)

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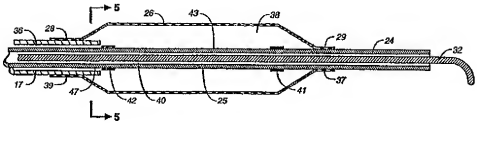
(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: A BALLOON CATHETER FOR CAUSING THERMAL TRAUMA TO A PATENT FORAMEN OVALE AND METHOD OF USING THE BALLOON CATHETER



(57) Abstract

This invention is a device and method for closing a patent foramen ovale comprising a catheter sheath (11) with proximal, and distal ends. A balloon catheter (16) is deploying retained within the catheter sheath. The fluid in the balloon can be heated using radio frequency (RF) energy via two electrodes (41, 42) contained within the balloon's lumen. The catheter is placed across a patent foramen ovale. The balloon catheter is advanced such that the balloon is deployed outside of the distal end of the catheter sheath. The catheter sheath is then removed from the foramen ovale, and the balloon is inflated within the foramen ovale. RF energy is then applied to the fluid in the balloon to heat the balloon to a temperature that causes thermal trauma to the lining of the foramen ovale. The balloon catheter is then deflated, repositioned into the distal end of the catheter sheath, and then removed from the patient.

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A BALLOON CATHETER FOR CAUSING THERMAL TRAUMA TO A PATENT FORAMEN OVALE AND METHOD OF USING THE BALLOON CATHETER

FIELD OF THE INVENTION

The present invention is related generally to medical/surgical devices that can be placed within the body of a patient to perform a procedure. More specifically, the present invention is a minimally invasive device useful in closing a patent foramen ovale.

BACKGROUND OF THE INVENTION

The fetal circulation is vastly different than the normal adult circulation. The blood circulating in a fetus is oxygenated by the placenta, not the developing lungs. Therefore, the fetal circulation directs only a small percentage of the circulating blood to the fetal lungs. Most of the circulating blood is shunted away form from the lungs to the peripheral tissues through specialized vessels and foramens that are open ("patent") during fetal life. In most people these specialized structures quickly close after birth, unfortunately, sometimes they fail to close and create hemodynamic problems that can be fatal if left untreated.

The fetal circulation is illustrated in Fig. 1. The umbilical arteries branch off of the iliac arteries and deliver unoxygenated (blue) blood to the placenta. The fetal blood travels through the capillary bed in the placenta and transfers carbon dioxide to the maternal blood and takes oxygen and other nutrients from the maternal blood. The umbilical vein returns oxygenated (red) blood to the fetus. Most of the oxygenated blood from the umbilical vein bypasses the developing liver and travels through a specialized vessel called the ductus venosus to the inferior vena cava and then into the right atrium. A good portion of the oxygenated blood from the inferior vena cava is directed across the right atrium and into the left atrium through a

specialized curtain like opening in the heart called the foramen ovale. The blood from the left atrium then enters the left ventricle and then into the aorta where it travels to the head and other body tissues delivering the needed oxygen and nutrients.

The small amount of blood entering the right atrium that does not pass through the foramen ovale, most of which comes from the superior vena cava, flows into the right ventricle and then gets pumped into the pulmonary trunk and pulmonary arteries. Some of this blood is pumped into the developing lungs. However, the fetal lungs are collapsed which causes a high resistance to blood flow. Another specialized vessel, called the ductus arteriosus, is a vessel that connects the high pressure pulmonary artery to the lower pressure aorta. Therefore, most of the blood in the pulmonary artery flows into the lower pressure aorta through this specialized vessel.

Upon birth, the circulatory system goes through profound changes. The flow through the umbilical arteries and umbilical vein stops and consequently the flow through the musculature around the ductus venosus constricts and the blood flow through the ductus venosus stops. The lungs fill with air and the resistance to blood flow into the lungs drastically decreases. The corresponding pressure in the right atrium, right ventricle, and pulmonary arteries also decrease. The decrease in pressure in the right atrium causes the curtain like opening of the foramen ovale to close, driving more blood into the right ventricle and then to the lungs for oxygenation. Over time, the foramen ovale is replaced with a membrane called the fossa ovalis. Similarly, the decrease in pressure in the pulmonary arteries reduced the pulmonary arterial pressure to the same as or slightly less than the pressure in the aorta, which stops or reverses the flow through the ductus arteriosus. Once the muscular tissue of the ductus arteriosus is perfused with well oxygenated blood, the muscle begins to constrict and close the ductus arteriosus. The ductus arteriosus normally closes within about one week of life.

Usually over time, the unique openings of the fetal circulation become obliterated and a solid mass of tissue forms where these opening once were. However, in some people the openings remain. A patent ductus venosus after birth

is very rare and almost always fatal. A patent ductus arteriosus occurs in about 1 out of every 5000 births. The patent ductus arteriosus once diagnosed is either medically treated or surgically ligated to close the ductus. In about one of four people, the foramen ovale does not seal shut, instead it remains patent. Since the pressure in the left atrium is about two to four mm Hg greater than the pressure in the right atrium, the curtain like opening usually remains shut. However, if the pressure in the right atrium increases, such as upon heavy lifting or while performing a Val Salva type maneuver, the curtain like fold of tissue opens and the blood flows from the right atrium to the left ventricle.

Studies have shown that adults with strokes of unknown origin (cryptogenic strokes) have about twice the normal rate of patent foramen ovales than the normal population. Although there is a correlation between strokes and patent foramen ovales, it is currently unknown why this correlation exists. Many people theorize that blood clots and plaque that have formed in the peripheral venous circulation (in the legs for example) break off and travel to the heart. Normally, the clots and plaque get delivered to the lungs where it is trapped and usually cause no harm to the patient. Patients with a patent foramen ovale, however, have a potential opening that the clots or plaque can pass through the venous circulation and into the arterial circulation and then into the brain or other tissues to cause a thromboembolic event like a stroke. The clots may pass to the arterial side when there is an increase in the pressure in the right atrium. Then the clots travel through the left side of the heart, to the aorta, and then to the brain via the carotid arteries where they cause a stroke and the associated neurological deficits.

Currently, the method of choice to close a patent foramen ovale is open heart surgery and ligation of the foramen ovale to close it. This obviously is associated with the usually risks of general anesthesia, open heart procedures, infections, etc. Another method is a catheter based method which places to opposing umbrella shaped devices around the foramen ovale, one in the right atrium and one in the left atrium. Unfortunately, this procedure is technically difficult and leaves behind two foreign objects that could dislodge or cause a thromboembolus which could break off and cause thromboembolic events. What is needed therefore is a least invasive

method for closing a patent foramen ovale which does not have the associated risk of an open heart procedure, is technically easy to perform, and which does not leave any foreign material behind.

SUMMARY OF THE INVENTION

The present invention provides a device and method for closing a patent foramen ovale. The present invention comprises a catheter sheath with proximal and distal ends. A balloon catheter is deployably retained within the catheter sheath. The fluid in the balloon is can be heated using radio frequency ("RF") energy via two electrodes contained within the balloon's lumen. Once the catheter sheath is placed by a treating health care professional across a patent foramen ovale, the balloon catheter is advanced such that the balloon is deployed outside of the distal end of the catheter sheath. The catheter sheath is then removed from the foramen ovale and the balloon is inflated within the foramen ovale. The treating healthcare professional then applies RF energy to the fluid in the balloon to heat the balloon to a temperature that causes thermal trauma to the lining of the foramen ovale. The balloon catheter is then deflated and then repositioned into the distal end of the catheter sheath and then removed from the patient. The traumatized area created along the inner surfaces of the patent foramen ovale heals over time and turns into a scar obliterating the foramen ovale.

BRIEF DESCRIPTION OF THE DRAWINGS

As used herein, like reference numerals will designate similar elements in the various embodiments of the present invention wherein:

Fig. 1 is a schematic diagram of the fetal circulation of a mammal;

Fig. 2 is a schematic diagram of a catheter of the present invention traveling up the inferior vena cava of a patient into the right atrium and through the foramen ovale;

Fig. 3 is a schematic plan view of a balloon foramen ovale catheter of the

present invention;

Fig. 4 is an axial cross-sectional view of the distal end of the catheter of Fig. 3;

Fig. 5 is a perpendicular cross-sectional view of the catheter of Fig. 3 taken along the plane indicated in Fig. 4 by line 5-5; and

Fig. 6 is an axial cross-sectional view of the proximal end of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention provides a novel least invasive device and method for closing a patent foramen ovale in a mammal. The device is specifically designed to be used in catheterization laboratories in hospitals for treating humans as well as veterinary hospitals for treating animals. As used herein the term "patient" shall refer to human patients as well as animal patients. As illustrated in Fig. 2, the device is introduced into the blood stream using well known catheterization procedures. The device is initially introduced within a catheter sheath 11 with a distal end 14. The device then extends distally from the catheter sheath to span the patent foramen ovale. The device has an inflatable balloon 26 with RF electrodes within the lumen of the balloon. The balloon is inflated while in the foramen ovale and RF energy is applied to thermally traumatize the interior tissue of the foramen ovale. After heat has been applied for sufficient amount of time, the balloon is deflated and the device is retracted into the catheter sheath. The device is then removed from the patient. Once the interior of the foramen ovale has been traumatized, the body's healing mechanism begins. Because the pressure within the left atrium is greater than the pressure in the right atrium, the curtains of tissue that comprises the patent foramen ovale are directly opposed to each other. The body's healing mechanism then replaces the traumatized tissue with scar tissue and the scar tissue forms across the curtain of tissue permanently sealing the foramen ovale. Over time, the foramen ovale becomes completely obliterated and turns into the normal fossa ovalis.

Turning now to Fig. 3, the foramen ovale catheter of the present invention is

further illustrated. In order to obtain access to the blood stream, the patent foramen catheter has to be advanced through the skin of the patient into a blood vessel, preferably a standard femoral vein catheterization is used that is well known in the art, however other vessel access to the atriums can be used. Typically, a standard introducer is used to gain access from the skin of the patient to the lumen of the vessel. These introducers are commercially available from many different manufacturers, Cordis Corporation of Miami Florida being one, Cook of Bloomington Indiana being another. The introducer can be of many different sizes, in the preferred embodiment the introducer varies from a 6 French to a 15 French introducer. Presently it is preferred to use a 7 or 8 French introducer.

A sheath catheter 11 is then advanced through the catheter port of the introducer. The outer diameter of the sheath catheter can vary from about 5 French to about 15 French. The inner diameter is such that a 4 French to about a 14 French foramen ovale catheter can be placed within its lumen. In the preferred embodiment, the sheath catheter is a single lumen catheter made by extruding standard catheter materials using standard extrusion techniques. Currently it is preferred to extrude polyether-block-amide, nylon, polyurethane, polyimide, or a polyolefin copolyester. However, any other extrudable catheter material well known in the art can be used to manufacture the catheter. The smaller the catheter, the stronger the extruding material should be. With very small catheters, the catheter can be reenforced by using braided meshing, a technique already well known in the catheter arts. The catheter has a proximal end 12 and a distal end 14. Provided at the proximal end is a port access 13 which allows the balloon catheter to be introduced through the sheath catheter. The sheath catheter's length is such that it can easily be used from a femoral site to reach an atrium of the heart, about 80 to 140 cm, with about 120 . cm being preferred. Optionally, the distal end of the sheath catheter can have a radio-opaque marker 24 such as a metallic ring placed around the distal end or incorporated into the distal end such that the distal end is visible under imaging techniques such as fluoroscopy.

Inserted inside the sheath catheter's lumen is a foramen ovale catheter 16 of the present invention. The catheter has a proximal end 18 provided with a standard

"Y" fitting 19 and a distal end 24. The Y fitting comprises a standard port 21 for the placement of a guide wire 23. The guide wire can be any standard guide wire in the industry. Typically, the guide wire is made out of a coil and has a blunt distal end 32 to prevent damage to vessels when the catheter is advanced. The angled stem 20 of the Y fitting is provided with a lure lock type fitting 22 which is used to inject fluid to inflate the balloon. Typically a syringe is connected to the port to control the inflation and deflation of the balloon. The fluid used is preferably a physiological fluid that conduct RF energy such as saline. A standard cable 30 with optional connectors is also provided at the proximal end of the balloon catheter. The cable is connected to a supply 31 of RF energy. A standard grounding electrode (not illustrated) is also connected to the RF supply and the skin of the patient.

Located at the distal end of the foramen ovale balloon catheter is the balloon 26. Referring now to Figs. 3-5, the foramen ovale catheter is actually comprised of two catheters, the outer catheter 16 which is placed within the catheter sheath, and an inner catheter 25 which has a lumen 40 for the guide wire 23. The inner catheter is longer than the outer catheter, the length corresponding to the length of the balloon (about 1 to 2 cm) plus an additional amount for the movement of the free floating ring 27 that is bonded to the wires 31 that cover the balloon. The outer and inner catheters can be made by extruding standard catheter materials using standard extrusion techniques, just like the sheath catheter. The outer catheter typically has an outer diameter of about 6 French to about 14 French, with 8 French being presently preferred. Between the outer and inner catheter is an area 36 for fluid to communicate with the fluid port and the interior of the balloon. The inner catheter is sized to fit within the outer catheter leaving adequate room for the fluid space 36. Currently the inner catheter has an outer diameter of about 3 French to about 12 French with 6 French being presently preferred. The balloon 26 is bonded to the distal end 17 of the outer catheter with an appropriate adhesive 39 such as heat curable polyurethane and the like. The balloon is also bonded near the distal end 24 of the inner catheter using an adhesive 37. This creates the fluid cavity 38 of the balloon.

The balloon can be made of any standard medical grade balloon material that

can resist being damaged at relatively high temperatures. Currently it is preferred that the balloon is somewhat non-compliant and can resist deforming at high temperatures and thus a balloon manufactured from poly-ethylene-terephthalte ("PET") or nylon is presently preferred. The balloon can vary in length from about 5 mm to about 25 mm with 10 mm being presently preferred. The balloon's diameter can also vary from about 3 mm to about 20 mm, with a diameter of 5 mm being presently preferred.

Located within the balloon's lumen 38 are two electrodes bonded to the inner catheter. The proximal electrode 42 is bonded near the proximal end of the balloon, and the distal electrode 41 is bonded near the distal end of the balloon. Lead wires 46 and 47 are provided for the electrodes between the inner and outer cathcters. The lead wires span from the cable at the proximal end to the electrodes at the distal end. Means for measuring the temperature within the balloon is optionally provided. Currently a thermocouple 43 is provided using standard copper and constantan wires 48. The thermocouple is ideally bonded to the inner catheter at the midpoint of the balloon.

The RF energy is typical RF energy ranging from about 100 kHz to about 1000 kHz, with about 460 kHz being presently preferred. The watts of power can vary from about 0.1 watt to about 100 watts, with a range of about 3 watts to 25 watts being presently preferred. Many different RF generators can be used to supply the RF energy. Presently, an RF generator manufactured by Stellartech Research Corporation of Mountain View, CA is preferred. The RF generator can deliver a maximum wattage of RF energy, with that maximum wattage chosen by the user of the generator. The RF generator then can measure the temperature at a thermocouple inside the needle to then regulate the wattage to maintain a set temperature. ~~Presently, temperatures ranging from about 45 degrees centigrade to~~ about 99 degrees centigrade is used with a temperature of 85 degrees centigrade being presently preferred. The RF energy can be delivered for a set time ranging from 1 second to 500 seconds with 30 seconds being presently preferred.

Turning now to Fig. 6, a preferred Y type fitting 19 is illustrated. The proximal end of the outer catheter 16 is bonded in the distal end 53 of the Y fitting

with bonding material 52. The proximal end of the inner catheter extends proximally past the fluid port 20 and is bonded in the middle of the Y fitting with bonding material 51. Thus, as can be appreciated by the drawing, the lumen 58 of the fluid port is in direct communication with the fluid space 36 between the inner and outer catheters. The guide wire port 57 at the most proximal end of the Y fitting is slightly tapered. The taper then increases to a conical section 54 until the inner diameter 55 is about identical to the inner diameter of the inner catheter. The tapering makes it easy to place the guide wire through the lumen 40 of the inner catheter. The cable 30 is connected to the Y fitting opposite the Y arm 20. The lead wires and thermocouple wires traverse through the Y fitting and into the space between the inner and outer catheters.

Those acquainted with medical procedures will appreciate that any medical procedure involving the heart should be practiced only by health care professionals with extensive training and experience in cardiology and/or cardiac surgery. Therefore the present invention provides for a method of training a person to perform the procedure of traumatizing a patent foramen ovale using the disclosed embodiments. The method of training includes the steps of demonstrating the device, supervising the person being trained, and the labeling instructions included with the device on when and how to use the device.

The embodiments of the present invention are all used similarly. Fist the shape and size of the foramen ovale is determined using standard imaging techniques such as magnetic resonance imaging, trans-esophageal echocardiography, and the like. Once the shape and size is determined, an appropriate sized balloon can be used to fill the inside of the patent foramen ovale. Then, access is gained to a blood vessel. Typically the femoral vein is catheterized using any one of may commercially available introducing catheters that are well known in the art. Once the introducing catheter is in place, a single lumen catheter that is long enough to reach the foramen ovale and is large enough to allow the particular embodiment of the present invention to pass through the lumen is placed through the introducing catheter. An example of this type of catheter is the 8 French Mullins Introducer Set manufactured by Cook of Bloomington IN. Typically these catheters are provided

with a fairly stiff guide wire to allow for probing the right atrium for the foramen ovale. The single lumen catheter is advanced to the right atrium and then through the foramen ovale to the left atrium.

Next the guide wire is removed and the foramen ovale catheter is advanced in the single lumen catheter to the left atrium. The single lumen catheter is then removed from the left atrium and the foramen ovale.

The balloon catheter is then placed within the foramen ovale by slowly withdrawing the catheter back from the left atrium towards the right atrium. The balloon is then positioned within the foramen ovale. Once in position, the balloon is inflated and RF energy is applied to raise the temperature within the balloon to the desired temperature, with 85 degrees centigrade being presently preferred. The temperature is applied for a sufficient time to cause thermal damage to the interior of the foramen ovale, currently for 30 seconds. The balloon is then deflated and the foramen ovale catheter is withdrawn into the single lumen catheter and then removed from the patient. All the catheters are then removed and the puncture site is sealed using standard techniques.

The trauma created within the foramen ovale starts a healing process which over time seals the foramen ovale shut with scar tissue. Once the foramen ovale is shut, the patient no longer has the risks associated with an patent foramen ovale.

While several particular embodiments of the invention have been illustrated and described, it will be apparent that various modifications can be made without departing from the spirit and scope of the invention. Accordingly, it is not intended that the invention be limited except as by the appended claims.

What is Claimed is:

1. An radio frequency balloon catheter device for thermally traumatizing a patent foramen ovale comprising:

A a sheath catheter with proximal and distal ends;

B a foramen ovale balloon catheter deployably retained within the sheath catheter, the foramen ovale catheter having proximal and distal ends;

C an inflatable balloon attached near the distal end of the foramen ovale balloon catheter;

D At least two radio frequency electrodes attached to the foramen ovale catheter within the balloon;

E means for inflating the balloon with a fluid; and

F a supply of radio frequency energy attached to the electrodes whereby applying radio frequency energy to the electrodes heats the fluid within the balloon when the balloon is inflated.

2. The catheter device of claim 1 wherein the foramen ovale balloon catheter comprises an outer catheter and an inner catheter.

3. The catheter device of claim 2 wherein the inner catheter is longer than the outer catheter.

4. The catheter device of claim 3 wherein the balloon, outer catheter, and inner catheter all have proximal and distal ends and wherein the proximal end of the balloon is attached to the distal end of the outer catheter and wherein the distal end of the balloon is attached to the inner catheter.

5. The catheter device of claim 1 wherein there are two radio frequency electrodes, the first one is located within the balloon near the balloon's proximal end and the second one is located within the balloon near the

balloon's distal end.

6. The catheter device of claim 1 further comprising a Y fitting attached to the proximal end of the foramen ovale balloon catheter.

7. The catheter device of claim 6 further comprising a cable connecting the radio frequency supply to the Y fitting.

8. The catheter device of claim 1 further comprising means for monitoring the temperature within the balloon.

9. The catheter device of claim 8 wherein the temperature monitoring means comprises a thermocouple attached to the foramen ovale balloon catheter at its distal end within the balloon.

10. A method of thermally traumatizing a patent foramen ovale comprising the steps of:

A inserting an introducer catheter into a vessel of a patient with a patent foramen ovale;

B inserting a foramen ovale balloon catheter with proximal and distal ends and a balloon attached near its distal end and with at least two electrodes attached to the foramen ovale catheter within the balloon;

C advancing the foramen ovale balloon catheter through the patent foramen ovale;

D inflating the balloon with a radio frequency energy conducting fluid;

E applying radio frequency energy for a sufficient time to the electrodes to thereby heat the fluid within the balloon and to thereby thermally traumatize the adjacent tissue of the patent foramen ovale;

F deflating the balloon; and

G removing the foramen ovale catheter and the introducer catheter from the patient.

11. The method of thermally traumatizing a patent foramen ovale of claim 10 further comprising the step of inserting a sheath catheter through the introducer catheter.

12. A method of training a person to perform the method of thermally traumatizing a patent foramen ovale comprising the steps of demonstrating or instructing the performance of the method of claim 10.

13. The method of training a person of claim 17 further comprising the step of claim 11.

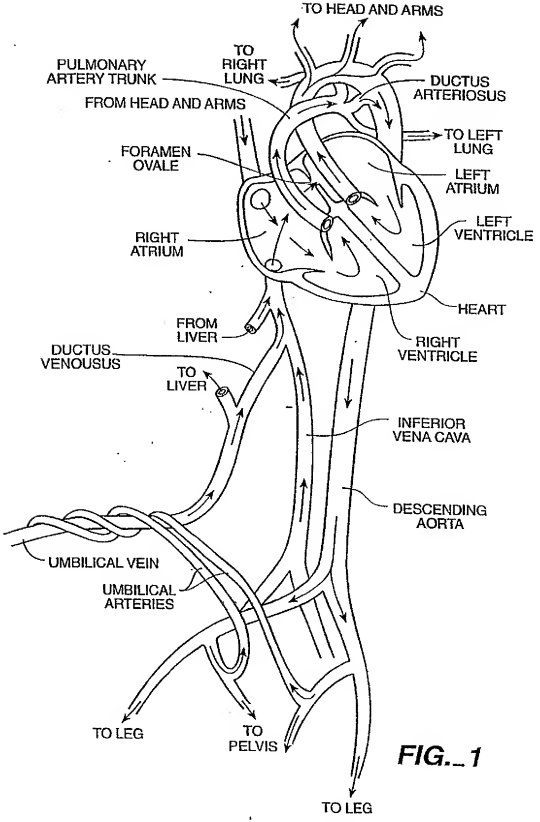
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FIG._1

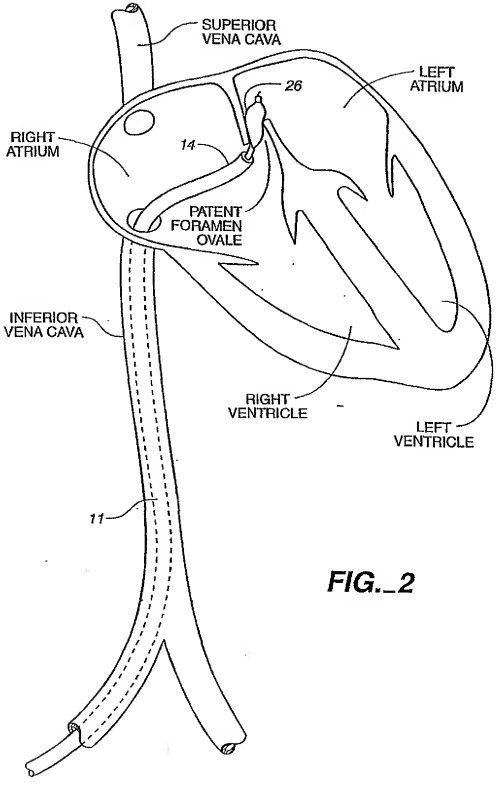
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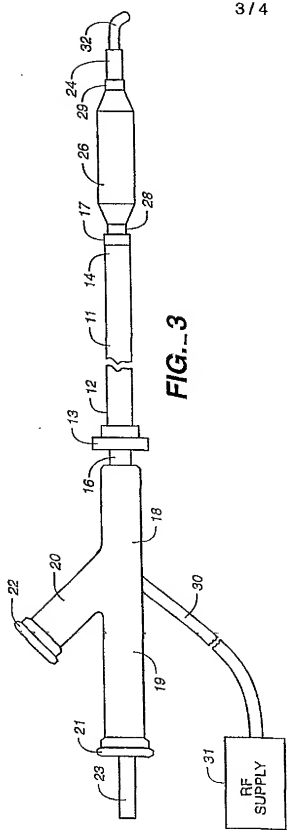
FIG._2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RF SUPPLY

FIG._3

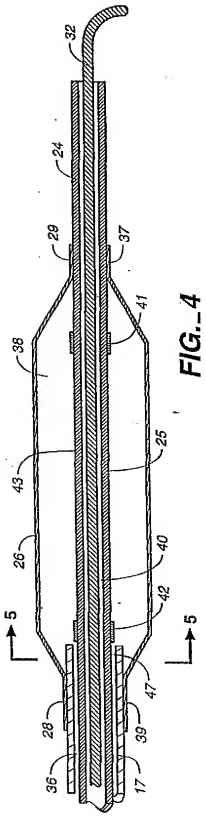
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FIG._4

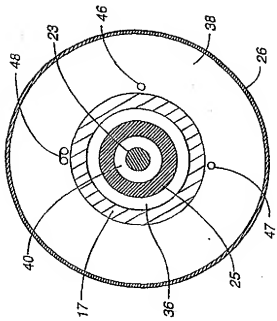
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FIG._5

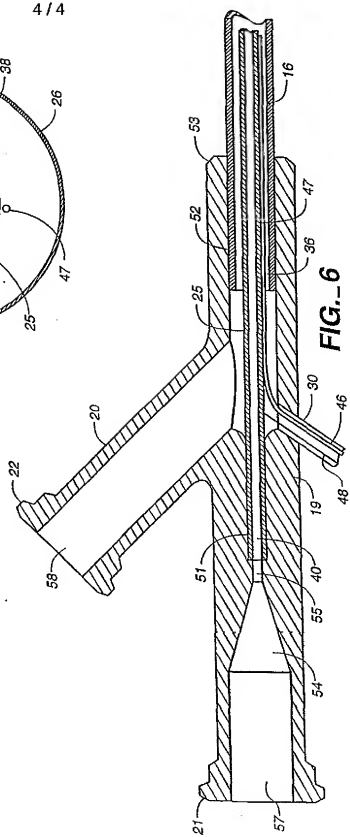
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FIG._6

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/21440

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/39
US CL :606/27-31, 41, 45, 49, 50; 607/99-102, 112

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/27-31, 41, 45, 49, 50; 607/99-102, 112

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

NONE

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,114,423 A (KASPRZYK et al) 19 May 1992, entire document.	1-4, 6-9
Y	US 5,151,100 A (ABELE et al) 29 September 1992, entire document.	1, 5
Y	US 5,496,311 A (ABELE et al) 05 March 1996, entire document.	1, 5
Y	US 5,564,440 A (SWARTZ et al) 15 October 1996, entire document.	1, 5
Y	US 5,571,088 A (LENNOX et al) 05 November 1996, entire document.	1, 5-9

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search	Date of mailing of the international search report
15 DECEMBER 1998	29 JAN 1999
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer ROY GIBSON
Facsimile No. (703) 305-3230	Telephone No. (703) 308-3520

Form PCT/ISA/210 (second sheet)(July 1992)*

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US98/21440

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ **Claims Nos.:**
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ **Claims Nos.:**
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☒ **Claims Nos.: 13**
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.